



[Billing Code: 6750-01S]

FEDERAL TRADE COMMISSION

Request for Comments and Announcement of Workshop on Pet Medications Issues

AGENCY: Federal Trade Commission (“FTC” or “Commission”)

ACTION: Reopening of the comment period for submission of public comments.

SUMMARY: The FTC is reopening the period for filing public comments in connection with a workshop to examine competition and consumer protection issues in the pet medications industry. The workshop will consider how current industry distribution and other business practices affect consumer choice and price competition for pet medications; the ability of consumers to obtain written, portable prescriptions that they can fill wherever they choose; and the ability of consumers to verify the safety and efficacy of pet medications that they purchase. The workshop will also examine the extent to which recent changes to restricted distribution and prescription portability practices in the contact lens industry might yield lessons applicable to the pet medications industry. The Commission seeks the views of consumers, veterinarians, business representatives, economists, lawyers, academics, and other interested parties on these issues. This notice poses a series of questions relevant to those issues about which the Commission seeks comment. After conducting the workshop and reviewing comments, the Commission may prepare a report discussing these issues.

DATES: The FTC is reopening the comment period and extending the deadline for filing public comments until November 1, 2012.

ADDRESSES: Interested parties are invited to submit written comments electronically or in paper form by following the instructions in the **SUPPLEMENTARY INFORMATION** section below. Comments in electronic form should be submitted by using the following Web link:

<https://ftcpublic.commentworks.com/ftc/petmedsworkshop> (and following the instructions on the

Web-based form). Comments filed in paper form should be mailed or delivered to the following address: Federal Trade Commission, Office of the Secretary, Room H-113 (Annex X), 600 Pennsylvania Avenue, NW, Washington, DC 20580, in the manner detailed in the **SUPPLEMENTARY INFORMATION** section below.

FOR FURTHER INFORMATION CONTACT: Stephanie A. Wilkinson, Attorney, Office of Policy Planning, Federal Trade Commission, 600 Pennsylvania Avenue, NW, Washington, DC 20580, 202-326-2084, petmedsworkshop@ftc.gov.

SUPPLEMENTARY INFORMATION:

The quality and cost of pet medications is an important pocketbook issue for many consumers. In 2011, 62 percent of U.S. households owned a pet, and Americans spent an estimated \$50 billion on their pets,¹ including nearly \$7 billion for prescription and over-the-counter (OTC) pet medications.² Drawing on the Federal Trade Commission's expertise as a competition and consumer protection agency, the workshop will examine ways to inform and empower consumers to obtain the highest quality and most cost-effective healthcare products for their pets.

Pet owners spend significantly more money on their pets than in past decades, and the market for pet medications has grown significantly in recent years.³ Manufacturers and veterinarians have introduced new and improved diagnostic and therapeutic treatments for pets; pet medications have become available at some online and brick-and-mortar retail outlets; and veterinarians and others have increasingly emphasized preventative pet care. In addition, market

¹ American Pet Products Association Industry Statistics & Trends.

² Packaged Facts estimates.

³ The size of the overall U.S. pet industry grew steadily from \$17 billion in 1994 to over \$50 billion in 2011. (American Pet Products Association Industry Statistics & Trends.) The size of the U.S. pet medications market grew from approximately \$4.5 billion in 2006 to approximately \$6.7 billion in 2011, and is projected to reach \$9.25 billion by 2015. (Packaged Facts estimates.)

participants note, in recent years it has become easier to administer flea and tick control products and heartworm preventatives, and the products themselves have become more effective. These products comprise the bulk of chronic pet medications sold in the United States. Indeed, the sale of prescription and OTC flea, tick, and heartworm products totaled nearly \$3.7 billion in 2011.⁴

Distribution Practices in the Pet Medications Industry

Historically, veterinarians have been the principal dispensers of pet medications because of their unique role in the veterinarian-client-patient relationship, whereby a veterinarian examines, diagnoses, and treats the animal (patient), while also providing information to the animal's owner (client). Consumers still purchase most of their pet medications from the veterinarians who examine their pets, and most pet medication manufacturers choose to distribute their products exclusively through the veterinary channel.

Nonetheless, pet medications are no longer sold exclusively by veterinarians. Over the last ten years, brick-and-mortar and online retail and pharmacy entities (hereinafter collectively referred to as "retailers") also have begun selling pet medications, especially OTC medications. Some evidence suggests that these retailers may offer substantial pro-consumer benefits, such as increased convenience and lower prices.

Although retailers may obtain some portion of their pet medication products directly from manufacturers or authorized distributors, they also rely heavily on secondary supply channels. Most manufacturers state that they restrict the distribution of their pet medications to the veterinary channel, and that they use well-established tracking procedures to ensure the safety and efficacy of their products. Certain veterinarians purchase pet medications from

⁴ *Id.* Of the estimated \$6.7 billion in U.S. retail sales of pet medications in 2011, 36% was for flea and tick control products, and 19% was for heartworm preventatives. (Packaged Facts estimates.)

manufacturers or authorized distributors and then resell some portion of their purchase to secondary suppliers for a profit, a practice sometimes referred to as “diversion.”⁵ Some secondary suppliers and retailers claim to have protocols in place to verify that the retailers receive bona fide products that originated with the manufacturer. Other industry participants, however, have questioned whether secondary suppliers and retailers always receive bona fide products (as compared to, for example, counterfeit product from non-U.S. sources), thereby raising potential questions about product safety and authenticity. The workshop will examine how competition in sales of pet medications to consumers has developed in light of these practices and how prices, product supply, and product quality may be affected.

In the workshop, the Commission seeks to examine issues related to the distribution of pet medications from practical, economic, and legal perspectives. The Commission invites public comment on questions relevant to this topic, including:

- How are pet medications distributed to consumers?
- What are the business rationales for various pet medication distribution practices?
- How has competition to sell medications to pet owners evolved in light of these distribution practices?
- How do these practices affect prices to consumers?
- How do these practices affect product supply and quality?
- How do these practices affect consumer choice?
- How do these practices affect entry into the pet medications market?

⁵ It should be noted that the term “diversion” as used in human pharmaceutical markets means the illegal trade in prescription narcotics, in which products are not being used by the consumer in the manner intended. This is distinct from the situation in the pet medications market, in which products obtained through secondary supply channels *are* being used by the consumer in the manner intended.

- How do these practices affect innovation in the pet medications market?
- What efficiencies or inefficiencies are associated with these practices?
- What, if any, product safety or counterfeiting issues exist with respect to these practices?

Have there been instances in which false or misleading information about product safety risks was disseminated to consumers?

- Are there other factors that should be considered when analyzing the competition and consumer protection issues related to the distribution of pet medications?

Prescription Portability for Pet Medications

All industry participants agree that pets should be properly examined and diagnosed by a veterinarian to determine the most appropriate course of treatment for any medical condition, including whether any medication should be prescribed. When a veterinarian writes a prescription for a medication to be dispensed and subsequently administered by a pet's owner, the prescription must be filled with the correct medication and dosage and the owner must have access to relevant information about the medication and proper administration techniques. Some observers argue that veterinarians are in the best position to carry out these responsibilities; these observers believe, therefore, that veterinarians alone should dispense prescription pet medications to their clients. Others argue that licensed pharmacists are equally capable of dispensing pet medications to consumers, provided the pharmacists dispense the correct medication and dosage as prescribed by a veterinarian; these advocates point out that veterinarians can still provide relevant information and follow-up care to their clients even if they do not dispense the medication. Concerns about the safety of pet medications dispensed by pharmacists appear less pronounced for OTC medications, which do not require a prescription and typically do not require direct supervision by a veterinarian.

A consumer cannot legally obtain prescription pet medications from a retailer without a written, portable prescription from a veterinarian. The American Veterinary Medical Association (AVMA) advises veterinarians to honor a client's request for a prescription, provided that a valid veterinarian-client-patient relationship exists.⁶ This guidance is not mandatory, however. State regulations vary as to whether veterinarians are legally required to provide written prescriptions to clients, and it is unclear to what extent such regulatory obligations may be actively enforced against veterinarians. It appears that, while many veterinarians provide written prescriptions to their clients when requested, some veterinarians have refused to provide prescriptions or otherwise have discouraged their clients from obtaining pet medications from retailers.

Federal legislation proposed in House Bill 1406 ("H.R. 1406" or "the Bill") would require veterinarians to provide clients with written prescriptions for all pet medications, regardless of whether requested, and to inform clients of their right to have pet medications dispensed elsewhere.⁷ The Bill also would prohibit veterinarians from charging a fee or requiring waivers of liability for providing written prescriptions. H.R. 1406 would require the Federal Trade Commission to promulgate rules implementing the statute within 180 days of its enactment.

In the workshop, the Commission seeks to examine issues related to the portability of pet medication prescriptions from practical, economic, and legal perspectives. The Commission invites public comment on questions relevant to this topic, including:

⁶ See Principles of Veterinary Medical Ethics of the AVMA, III.C.1.

⁷ See Fairness to Pet Owners Act, H.R. 1406, 112th Cong. (2011), *available at* <http://www.gpo.gov/fdsys/pkg/BILLS-112hr1406ih/pdf/BILLS-112hr1406ih.pdf>.

- How varied are current veterinarian practices with respect to providing written, portable prescriptions to clients?
- To what extent are consumers aware that they can request a portable prescription from their veterinarian and have the prescription dispensed elsewhere?
- Which states require prescription portability for pet medications? Which do not? Are there states in which a proposal for prescription portability for pet medications was rejected by the legislature and, if so, why?
- In states that do require prescription portability, what recourse do consumers have if a veterinarian refuses to provide a written, portable prescription?
- What evidence exists to support a need for federal legislation requiring veterinarians to provide written prescriptions to their clients?
- What price and non-price benefits can accrue to consumers from prescription portability for pet medications?
- What risks or inefficiencies may be posed by prescription portability for pet medications?
- Is there a need for federal legislation requiring veterinarians to notify clients that they have the right to fill their prescriptions at the pharmacy of their choice?
- Is it appropriate to deny veterinarians the ability to charge a fee or require a waiver of liability for providing a written prescription to clients?
- How might the passage of H.R. 1406 affect price, consumer choice, and other forms of competition in the pet medications market?
- How can the prices charged to consumers for pet medications by veterinary clinics and retailers best be quantified and compared?

- To what extent do retailer prices for pet medications affect the prices of medications sold at veterinary practices, or other aspects of veterinary clinic operations?
- To what extent would H.R. 1406 affect veterinarians' sales of pet medications?
- What compliance costs would veterinarians face if H.R. 1406 were enacted?
- How might the passage of H.R. 1406 affect pet medication distribution practices?
- Should possible amendments to H.R. 1406 be considered?
- Are there other factors that should be considered when analyzing the competition and consumer protection issues related to the portability of pet medication prescriptions?

Comparison to Fairness to Contact Lens Consumers Act

Some restricted distribution and prescription portability issues existed in the contact lens industry at the time that Congress passed the Fairness to Contact Lens Consumers Act (“FCLCA”), Public Law 108-164. Industry participants have noted both similarities and differences between the contact lens industry and the pet medications industry. The workshop will examine whether consumer experiences with the FCLCA might provide insights about the potential impact of H.R. 1406. The Commission invites public comment on questions relevant to this topic, including:

- What was the impact of the FCLCA, if any, to consumers?
- What was the impact of the FCLCA, if any, to optometrists and ophthalmologists?
- What was the impact of the FCLCA, if any, on entry into the contact lens industry?
- What was the impact of the FCLCA, if any, on innovation in the contact lens industry?
- What was the impact of the FCLCA, if any, to contact lens distribution practices?
- Are there significant similarities or differences between the contact lens industry and the pet medications industry, particularly with respect to industry distribution practices and

issues of prescription portability? If so, how should those similarities or differences be taken into account in assessing the likely effects of H.R. 1406 compared to the FCLCA?

- Are there other factors that should be considered when analyzing the competition and consumer protection issues related to the FCLCA, and how consumer experiences with the FCLCA might provide insights about the potential impact of H.R. 1406?

Instructions for Filing Public Comments

Interested parties are invited to submit written comments electronically or in paper form. The deadline for receiving comments has been extended to November 1, 2012. Because paper mail addressed to the FTC is subject to delay due to heightened security screening, please consider submitting your comments in electronic form. Comments filed in electronic form should be submitted using the following Web link:

<https://ftcpublic.commentworks.com/ftc/petmedsworkshop> (and following the instructions on the Web-based form). To ensure that the Commission considers an electronic comment, you must file it on the Web-based form at the Web link:

<https://ftcpublic.commentworks.com/ftc/petmedsworkshop>. If this notice appears at <http://www.regulations.gov/#!/home>, you may also file an electronic comment through that Web site. The Commission will consider all comments that regulations.gov forwards to it. You may also visit the FTC Web site at <http://www.ftc.gov> to read the notice and the news release describing it.

Comments should refer to “Pet Medications Workshop, Project No. P12-1201” to facilitate the organization of comments. Please note that your comment – including your name and your State – will be placed on the public record of this proceeding, including on the publicly accessible FTC Web site, at <http://www.ftc.gov/os/publiccomments.shtm>. Because comments

will be made public, they should not include any sensitive personal information, such as any individual's Social Security Number; date of birth; driver's license number or other State identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. Comments also should not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, comments should not include "trade secret or any commercial or financial information which is . . . privileged or confidential" as discussed in Section 6(f) of the Federal Trade Commission Act (FTC Act), 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled "Confidential," and must comply with FTC Rule 4.9(c).⁸

A comment filed in paper form should include the "Pet Medications Workshop, Project No. P12-1201" reference both in the text and on the envelope, and should be mailed or delivered to the following address: Federal Trade Commission, Office of the Secretary, Room H-113 (Annex X), 600 Pennsylvania Avenue, NW, Washington, DC 20580. The FTC is requesting that any comment filed in paper form be sent by courier or overnight service, if possible, because U.S. postal mail in the Washington area and at the Commission is subject to delay due to heightened security precautions. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives, whether filed in paper or electronic form. Comments received will be available to the public on

⁸ The comment must be accompanied by an explicit request for confidential treatment, including the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. The request will be granted or denied by the Commission's General Counsel, consistent with applicable law and the public interest. *See* FTC Rule 4.9(c), 16 CFR 4.9(c).

the FTC Web site, to the extent practicable, at <http://www.ftc.gov/os/publiccomments.shtm>. As a matter of discretion, the FTC makes every effort to remove home contact information for individuals from the public comments it receives before placing those comments on the FTC Web site. More information, including routine uses permitted by the Privacy Act, may be found in the FTC's privacy policy, at <http://www.ftc.gov/ftc/privacy.htm>.

By direction of the Commission.

Donald S. Clark
Secretary.

[FR Doc. 2012-23464 Filed 09/21/2012 at 8:45 am; Publication Date: 09/24/2012]